PATENT *John*

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: John Kevin COLLINS et al. Attorney Docket: P66877US2

Serial No.: 10/804,223

Group Art Unit: 1614

Filing Date: March 19, 2004

Examiner: n/a

For: USE OF LACTOBACILLUS SALIVARIUS

## TRANSMITTAL

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Transmitted herewith is an Information Disclosure Statement in the above captioned application.

XX Small Entity status of this application under 37 C.F.R. 1.9 and 1.27 has been established by a verified statement previously submitted.

XX Information Disclosure Statement, Form PTO-1449 and references.

The fee has been calculated as shown below:

Claims	Highest	Present	Small Entity	Other Than A
Remaining	Number	Extra		Small Entity
After	Previously		Rate Addit. (or)	Rate Addit.
Amendment	Paid For		Fee	Fee
Total 45	- 45	= 0	x25 = \$	x 50 = \$
Indep. 4	- 4	= 0	x100 = \$	x 200 = \$
Total Additional Fee			\$	\$

\_\_\_\_ Credit Card Payment Forms in the amount of \$\_\_\_\_ are attached.

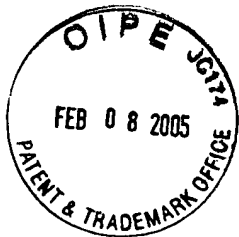
XX If a Petition for Extension of Time is necessary and the Petition and/or the check is not enclosed, this will act as the Petition and applicant herewith petitions the Commissioner to extend the time for response and charge any fees necessary under 37 CFR 1.17 (a)(1)-(5) to Deposit Account No. 06-1358. The Commissioner is also authorized to charge payment of any other additional fees associated with this communication or credit any overpayment to Deposit Account No. 06-1358. A duplicate copy of this sheet is attached.

JACOBSON HOLMAN, PLLC

Dated: February 8, 2005  
400 Seventh Street, N. W.  
Washington, D.C. 20004-2201  
P66877US2  
JCH/JC

By: *John C. Holman*  
John C. Holman  
Reg. No. 22,769

*1*



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

COLLINS et al.

Confirmation No.: 6092

Serial No.: 10/804,223

Group Art Unit: 1614

Filed: March 19, 2004

Examiner: Not Yet Assigned

For: USE OF LACTOBACILLUS SALIVARIUS

**INFORMATION DISCLOSURE STATEMENT**

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

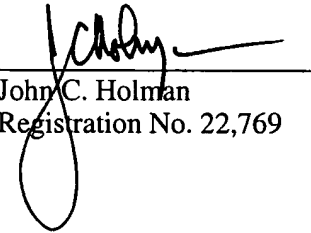
As a means of complying with the duty of disclosure under 37 CFR §1.56, and in accordance with 37 CFR §§1.97 and 1.98, Applicants, through the undersigned attorney, submits this Information Disclosure Statement. The patents, publications or other information submitted herewith are listed on the attached Form PTO-1449 and copies are attached excluding U.S. patents and publications.

In accordance with 37 CFR §1.97(b)(3), this Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits of the above-identified application.

Respectfully submitted,

JACOBSON HOLMAN PLLC

By: \_\_\_\_\_

  
John C. Holman  
Registration No. 22,769

400 Seventh Street, N.W.  
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Atty. Dkt. No.: P66877US2  
Date: February 8, 2005  
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## LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT

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## U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE (If Appropriate)
	AA	4,347,240	8-31-82	MUTAI			
	AB	4,435,389	3-6-84	MUTAI			
	AC	5,032,399	7-16-91	GORBACH			
	AD	5,711,977	1-27-98	YANG			
	AE	5,834,423	11-10-98	KOKETSU			
	AF	5,922,375	7-13-99	LUCHANSKY			
	AG	6,077,504	6-20-00	CAVALIERE V. VESLEY			
	AH	6,025,008	2-15-00	AKAHOSHI			
	AI	6,132,710	10-17-00	PANIGRAHI			
	AJ	6,368,591	4-9-02	CHEN			
	AK	6,645,530	11-11-03	BORODY			
	AL	6,746,671	6-8-04	STEIDLER			
	ALA	5,443,826	8-22-95	BORODY			

## FOREIGN PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	Translation (Yes) (No)	
	AM	WO89/05849	6-24-89	WIPO				
	AN	WO90/09398	8-23-90	WIPO				
	AO	WO90/01335	2-22-90	WIPO				
	AP	WO97/35596	10-2-97	WIPO				
	AQ	WO98/00035	1-8-98	WIPO				
	AR	WO98/35014	8-13-98	WIPO				
	AS	WO99/51631	10-14-99	WIPO				
	AT	WO99/62348	12-9-99	WIPO				
	AU	WO00/42168	7-20-00	WIPO				
	AV	WO01/37865	5-31-01	WIPO				
	AW	WO01/85774	11-15-01	WIPO				
	AX	WO02/058712	8-1-02	WIPO				
	AY	WO02/083879	10-24-02	WIPO				
	AZ	EP 384319B	4-28-99	EPO				

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## FOREIGN PATENT DOCUMENTS (continued)

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTR Y	CLASS	SUB- CLASS	Translation	
							(Yes)	(No)
	BA	EP508701B	7-10-96	EPO				
	BB	EP904784A	3-31-99	EPO				
	BC	EP1312667A	5-21-03	EPO				
	BD	GB1503094	3-8-78	U.K.				
	BE	RU2091075	4-20-98	RUSSIA			ABSTRACT	
	BF	RU2055827	3-10-96	RUSSIA			ABSTRACT	
	BG	JP05246864	9-24-93	JAPAN			ABSTRACT	
	BH	JP9241173	9-16-97	JAPAN			ABSTRACT	
	BI	SU1382467	3-23-88	RUSSIA				
	BJ	DE19945746	4-19-01	GERMANY			ABSTRACT	
	BK	KR2003063960	7-31-03	KOREA			ABSTRACT	
	BL	RU2109054	4-20-98	RUSSIA			ABSTRACT	
	BM	RU20001160	9-7-93	RUSSIA			ABSTRACT	

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INITIALS

_____	<u>BN</u>	Kim YC, Jeong HK, Kim SH, Moon IL, Kim BC, The properties of Bifidobacteria isolate from healthy Koreans, Korean J Dairy Sci, 20(3):191-204, 1998.
_____	<u>BO</u>	Feeney, M., Morrissey, D., O'Sullivan, GC, Shanahan, F., Collins, JK. 1998. Lack of specific systemic immune response on oral consumption of probiotic lactobacilli. International Dairy Journal 8, No 5/6, 1998 Published Oct 16, 1998. Abstract from a meeting held in Cork, Ireland 30Sept -2 Oct 1997.
_____	<u>BP</u>	Flynn, S. G.M. Thornton, D. Morrissey, J.K. Collins. (1998). Isolation and characterisation of the novel antibacterial proteins ABP-1 and ABP-118 from human isolates Lactobacillus salivarius ssp. salivarius UCC1 and UCC118. International Dairy Journal 8, No 5/6, 1998 Published Oct 16, 1998. Abstract from a meeting held in Cork, Ireland 30Sept -2 Oct 1997.
_____	<u>BQ</u>	Charteris WP, Kelly PM, Morelli L, Collins JK. Antibiotic susceptibility of potentially probiotic Lactobacillus species. J Food Prot. 1998 Dec;61(12):1636-43.
_____	<u>BR</u>	Charteris WP, Kelly PM, Morelli L, Collins JK. Antibiotic susceptibility of potentially probiotic Bifidobacterium isolates from the human gastrointestinal tract. Lett Appl Microbiol. 1998 May;26(5):333-7.
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_____	<u>BT</u>	Collins JK, Thornton G, O'Sullivan G. Selection of probiotic strains for human applications. Int Dairy Journal. 1998, 8: 487-490.
_____	<u>BU</u>	Gardiner G, Ross RP, Collins JK, Fitzgerald G, Stanton C. Development of a probiotic cheddar cheese containing human-derived Lactobacillus paracasei strains. Appl Environ Microbiol. 1998 Jun;64(6):2192-9.
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_____	<u>BW</u>	Kato D, et al "suppressive effects of the oral administration of L.casei on Type II collagen-induced arthritis inn DBA/1 mice" Life Sciences, Vol 63, No. 8 1998, pp 635-644.
_____	<u>BX</u>	Morrissey D, Murphy L, Marteau P, Kiely B, Fitzgerald G, Daly C, O'Sullivan G, Shanahan F, Collins JK. (1998) Selection of a probiotic strain to modify human gut flora and a controlled trial of delivery and efficacy. Ir. J. Med Sci. 167; 8: 7 Abstract from meeting of Irish Society for Gastroenterology, June 12-13 1998
_____	<u>BY</u>	Murphy, L., Thornton, G., Marteau, P., Morrissey, D., O'Sullivan, GC, Shanahan, F., Collins, JK. 1998. Long-term colonisation with Lactobacillus salivarius ssp. salivarius UCC118: A probiotic candidate. International Dairy Journal 8, 595. No 5/6, Published Oct 16, 1998. Abstract from a meeting held in Cork, Ireland 30 Sept -2 Oct 1997.

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_____	<u>BZ</u>	O'Halloran S, Feeney M, Morrissey D, Murphy L, Thorton G, Shanahan F, O'Sullivan G, Collins JK. (1998) Adhesion of potential probiotic bacteria to human epithelial cell lines. International Dairy Journal 8, 596, No 5/6, 1998 Published Oct 16, 1998. Abstract from a meeting held in Cork, Ireland 30 Sept -2 Oct 1997.
_____	<u>CA</u>	O'Riordan, K, Condon, S, Fitzgerald, GF. 1998. Assessment of Bifidobacterium strains for microbial and exopolysaccharide production and evaluation of pulsed field gel electrophoresis as a method for identifying or discriminating between Bifidobacterial strains. International Dairy Journal 8,594.No 5/6, Published Oct 16, 1998. Abstract from a meeting held in Cork, Ireland 30 Sept -2 Oct 1997.
_____	<u>CB</u>	Collins J K, Probiotics and inflammatory bowel disease:animal models, Abstract from 3rd workshop Demonstration of the nutritional functionality of probiotic foods, FAIR CT96-1028, Functional Food Research in Europe, Haikko Manor, Finland 1-2 October 1998, pg 124.
_____	<u>CC</u>	Collins J K, Murphy L, O'Mahony L, Morrissey D, Feeney M, O'Halloran S, O'Donoghue M, Shanahan F, Kiely B, Fitzgerald G, O'Sullivan G, Demonstration of probiotic function in a double blind placebo controlled clinical trials in adults, Abstract from 3rd workshop Demonstration of the nutritional functionality of probiotic foods, FAIR CT96-1028, Functional Food Research in Europe, Haikko Manor, Finland 1-2 October 1998, pgs 40-41.
_____	<u>CD</u>	O'Riordan, K. and Fitzgerald, G.F. 1998. Evaluation of Bifidobacterium species for the production of antimicrobial compounds and assessment of performance in cottage cheese at refrigeration temperature. J. Appl. Microbiol. 85, 103-114.
_____	<u>CE</u>	Salminen S, Von Wright A, Morelli L, Marteau P, Brassert D, de Vos WM, Fonden r, Saxelin M, Collins JK, Mogensen G, Birkeland SE, Mattila-Sandholm T. (1998b) Demonstration of safety of probiotics. Int. Jnl. Food Micro. 44, 93-106.
_____	<u>CF</u>	Shanahan F, O'Sullivan GC, Collins JK. Genes, bacteria, and T cells: ingredients for inflammatory bowel disease. Gastroenterology. 1998 Dec;115(6):1595-1600.
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_____	<u>CH</u>	LAN, Jinggang. Immunopotentiating Activity of Bifidobacterium and its Significance. Foreign Medical Sciences: Clinic Biochemistry & Medical Test 1998, Vol. 19(5): 231-233
_____	<u>CI</u>	Gionchetti et al "Microflora in the IBD Pathogenesis Possible Therapeutic Use of Probiotics". Gastroenterology International. 1st International Meeting on Intestinal Microflora 1998. Vol. 11. Suppl. 1, pages 108 to 110
_____	<u>CJ</u>	Steidler L., K. Robinson, L. Chamberlain, K.M Scholfield, E. Remaut, R.W.F. Le Page and J.M. Wells. Mucosal delivery of murine interleukin-2 (IL-2) and IL-6 by recombinant strains of Lactococcus lactis coexpressing antigen and cytokine. Infect. Immun., 1998; 66:3183-9.
_____	<u>CK</u>	Aranda R. et al. J. of Immunol. 1997; 158(7), 3464-3473

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_____	<u>CL</u>	Charteris WP, Kelly PM, Morelli L, Collins JK. Selective detection, enumeration and identification of potentially probiotic Lactobacillus and Bifidobacterium species in mixed bacterial populations. Int J Food Microbiol. 1997 Mar 18;35(1):1-27. Review.
_____	<u>CM</u>	Favier, C. et al; Dig. Dis. Sci. 1997;42:817-822
_____	<u>CN</u>	Gahan GC, Barrett JR, O'Sullivan GC, Shanahan F, Collins JK. Innate resistance to Listeria monocytogenes in tumour bearing mice. J. Leucocyte Biology 1997; 62(6): 726-732.
_____	<u>CO</u>	Leonard JP, Waldburger KE, Schaub RG, Smith T, Hewson AK, Cuzner ML, Goldman SJ. Regulation of the inflammatory response in animal models of multiple sclerosis by interleukin-12. Crit Rev Immunol 1997;17(5-6):545-53.
_____	<u>CP</u>	Lucey, M., and Fitzgerald, G.F. 1997. Developing fields in biotechnology:Biotechnology of lactic acid bacteria. Food Science and Technology Today, 11.230-233.
_____	<u>CQ</u>	Madsen, K. et al. Gastroenterol. 1997;112:A1030.
_____	<u>CR</u>	McFarland et al Anaerobe, Vol 3, No.2-3, 1997, pages 73-78
_____	<u>CS</u>	O'Riordan, K. and Fitzgerald, G.F. 1997. Determination of genetic diversity within the genus Bifidobacterium and estimation of chromosomal size. FEMS Microbiol. Lett. 156, 259-264.
_____	<u>CT</u>	Schmitt E, Rude E, Germann T. The immunostimulatory function of IL-12 in T-helper cell development and its regulation by TGF-beta, IFN-gamma and IL-4. Chem Immunol 1997;68:70-85.
_____	<u>CU</u>	Shanahan F, and O' Sullivan GC. Grand entry for Listeria. Gastroenterology 1997, 112: 1045-1046.
_____	<u>CV</u>	Singh, J. et al Carcinogenesis 1997;18:833-841
_____	<u>CW</u>	Mattila-Sandholm T, Demonstration project FAIR2 CT96-1028, VTT Symposium 173 Article from 2nd workshop Demonstration of the nutritional functionality of probiotic foods FAIR CT96-1028, Novel methods of probiotic research, Cork Ireland, 3 October 1997, pgs 11-15.
_____	<u>CX</u>	Collins K, Probiotic Lactobacilli - towards defining selection and functional criteria, VTT Symposium 167 Abstract from 1st workshop Demonstration of the nutritional functionality of probiotic foods FAIR CT96-1028, Selection and safety criteria of probiotics, Helsinki Finland, 15 November 1996, pg 27.
_____	<u>CY</u>	Arihara, K et al XP-002072786 School of Veterinary Medicine and Animal Sciences, 1996 The Society for Applied Bacteriology
_____	<u>CZ</u>	Bouhnik Y. et al; Eur. J. Clin. Nutr. 1996;50:269-273
_____	<u>DA</u>	Collins JK, O'Sullivan G, Shanahan F, Probiotic bacteria- interaction with the human immune system. J. Roy. Soc. Med International Congress and Symposium Series -209 Royal Society of Medicine Press (1996) 219:13-17

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_____	<u>DB</u>	Daly, C., Fitzgerald, G.F. and Davis, R. 1996. Biotechnology of lactic acid bacteria with special reference to bacteriophage resistance. In: Lactic Acid Bacteria : Genetics, Metabolism and Applications, (Venema, G., Huis in't Veld, J.H.J. and Hugenholtz, J., eds), pp. 3-14. Kluiver Academic Publishers, London, U.K.
_____	<u>DC</u>	Halpern, G.M., et al, The American Journal of Gastroenterology, Vol. 91, No. 8, 1996.
_____	<u>DD</u>	Huis in't Veld J, Shortt C. Selection criteria for probiotic micro-organisms. In: Leeds, A.R., Rowland, I.R. eds. Gut Flora and Health - Past, Present and Future. London: The Royal Society of Medicine Press Ltd., 1996:19-26
_____	<u>DE</u>	Takiguchi, R. et al. Bifidus - Flores, Fructus et Semina 1996;9:135-140
_____	<u>DF</u>	Collins JK, Selection of probiotic strains and potential therapeutic applications, from Book of Abstracts for European Commission Biotechnology and Fair Programmes Cork Ireland 22-26 October 1995.
_____	<u>DG</u>	Thornton G, Murphy L, Flynn S, O'Sullivan G, Shanahan F, Collins JK, Determination of stringent criteria essential to the survival/growth/colonisation of probiotic human intestinal tract bacteria, from Book of Abstracts for European Commission Biotechnology and Fair Programmes Cork Ireland 22-26 October 1995.
_____	<u>DH</u>	Lee et al., Trends in Food Science & Technology, Vol. 6,pp.241-245 (July 1995)
_____	<u>DI</u>	Medaglini D., G. Pozzi, T.P. King and V.A. Fischetti. Mucosal and systemic immune responses to a recombinant protein expressed on the surface of the oral commensal bacterium Streptococcus gordonii after oral colonization. Proc. Natl. Acad. Sci. USA, 1995;92:6868-72.
_____	<u>DJ</u>	Sarem-Damerdjil Leila-ouassila, Sarem, Farzin, Marchal, Luc, Nicolas Jean-Pierre. "In vitro colonization ability of human colon mucosa by exogenous Lactobacillus strains. FEMS Microbiology Letters 131 (1995) 133-137.
_____	<u>DK</u>	Shanahan F. Pathogenic mechanisms in inflammatory bowel disease. In: Kasuya Y, Tsuchiya M, Matsuo Y, (editors) Gastrointestinal Function: Regulation and Disturbances Proceedings of the 13th symposium of the regulation and disturbances of gastrointestinal function, Tokyo, Nov 6, 1994. Excerpta Medica 1995;13: 13-28.
_____	<u>DL</u>	Thornton, G, O'Sullivan M, O'Sullivan G et al. Bile tolerance and bile salt hydrolase activity of lactobacilli and bifidobacteria isolated from the human intestine. Gastroenterology 108 (4) A928-A928 Suppl. S APR 1995
_____	<u>DM</u>	Yang H, Rotter JI. Genetics of inflammatory bowel disease. In Targan, SR. and Shanahan, F. eds. Inflammatory bowel disease: From bench to bedside. Williams and Wilkins 1994 (32-64).
_____	<u>DN</u>	Brink, B. ten M et al XP002072787 TNO Nutrition and Food Research, Department of Microbiology, Journal of applied Bacteriology 1994, 77, 140 148

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_____	<u>DO</u>	Thornton G, O'Sullivan M, O'Sullivan G, Weerkamp A, Shanahan F, Collins JK, Bile acid tolerance and deconjugating activity of lactobility, Irish Journal of Medical Science, Supplement with Proceedings of the Irish Society of Gastroenterology Meeting 25 and 26th Nov 1994.
_____	<u>DP</u>	Thornton G, O'Sullivan G, Collins JK The production of a novel anti-microbial substance by human intestinal microflora, Irish Journal of Medical Science, Supplement with Proceedings of the Irish Society of Gastroenterology Meeting 3and 4th June 1994.
_____	<u>DQ</u>	Thornton G, O'Sullivan G, Collins JK, Towards an understanding of the survival mechanism employed by the health promoting commensal flora of the human small intestine, Irish Journal of Medical Science, Supplement with Proceedings of the Irish Society of Gastroenterology Meeting 3 and 4th June 1994.
_____	<u>DR</u>	Zhang, Houde et al. Treatment of Acute Enteritis with Oral Administration of Short-Term High-Dose Bifidobacteria. Chinese Journal of Microecology, Vol. 6, No. 6, p. 47 (1994)
_____	<u>DS</u>	Kulkarni, N. and Reddy, B. Proc. Soc. Experim. Biol. Med. 1994;207;278-283.
_____	<u>DT</u>	Shanahan F, O' Sullivan GC, Collins JK (1994). Immunosuppressive agents in inflammatory bowel disease. " Inflammatory Bowel Disease: Basic Research, Clinical Implications". (Eds. Sutherland L.R., Collins S.M., Martin F., McLeod R., Targan S.R., Wallace J.L. and Williams C.N.) Kluwer academic publishers, Dordrecht, Netherlands.1994; 367.
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